add any new matter within the meaning of 35 U.S.C. §132 to the application. Entry is therefore respectfully requested.

1. Objection to the Specification - Claim to Priority

The Official Action states the following, in relevant part:

> It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/EP00/00324, filed 1/18/2000 or Application No 60/155,268, filed 1/19/1999. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120.

RESPONSE

Applicants thank the Examiner for her comments and suggestions regarding an amendment to the specification. Accordingly, applicants have submitted herewith, as Appendix B, an amendment to the specification to be entered at page 1, line 1 which references the priority application PCT/EP00/00324, filed January 18, 2000, which claims the benefit of U.S. Provisional Patent Application Serial No. 60/155,268, filed January 19, 1999, now abandoned.

It is respectfully noted that both of these applications also appear on the Official Filing Receipt of the present application. Further, the Notification of Missing Requirements

under 35 U.S.C. 371 in the United States Designated/Elected Office, mailed August 14, 2001, acknowledges receipt of the Priority document.

Accordingly, applicants respectfully request that the Examiner acknowledge applicants' claim to priority on the next Office communication to applicants.

2. Objection to the Specification - Abstract of the Disclosure

The Official Action states, in relevant part:

> This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

RESPONSE

Pursuant to the Examiner's request, an Abstract of the Disclosure has been submitted in accordance with 37 C.F.R. §1.72(b) as requested by the Examiner.

3. Rejection of claims 1-17 under 35 U.S.C. §112, 2nd paragraph

The Official Action states, in relevant part:

> Claims 1-17 [are] rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
>
> The metes and bounds of the limitation "at least

substantially the same as" or "which is the same as" in Claims 1-17 are not clear. How similar must the protein be to be considered "substantially the same" as recombinant SP-A? Moreover, what similarities must the protein have to be considered "the same" (e.g. must they have the same sequence? The same function and if so what function must be the same?) Clarification is required.

Claims 1-4 are indefinite because the claims are drawn to a method but there are no method steps and no endpoint for one to know when the method has been successfully practiced. If the claims were intended to be drawn to a method, including the steps of the method and an endpoint is required.

RESPONSE

Applicants have deleted all occurrences of the phrases "at least substantially the same as" and "which is the same as" throughout the claims, rendering the basis for this rejection of claims 1-17 moot. Further, claims 1-4 and 14 have been cancelled without prejudice to or disclaimer of the subject matter contained therein, rendering the basis for this rejection moot.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejections under 35 U.S.C. §112.

4. Rejection of claims 1-3, 5-11 and 16-17 under 35 U.S.C. §102(a)

The Official Action states, in relevant part:

Claims 1-3, 5-11 and 16-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Borron et al.

Borron et al. teach a composition comprising a recombinant SP-A that is identical to the composition presently claimed. The composition of Borron et al. is purified and the final preparation is lipid-free and contained in a buffer (considered a carrier) at neutral pH. Thus, the composition of Borron et al. appears to be identical to a lipid-free medicament composition of the claims.

RESPONSE

Applicants respectfully traverse this rejection. The Examiner has failed to establish a *prima facie* case of anticipation under 35 U.S.C. §102(a) because the cited reference fails to teach each and every element of the presently pending claims.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

With regards to the rejection of claims 1-3, applicants

respectfully point out to the Examiner that claims 1-3 have been cancelled without prejudice to or disclaimer of the subject matter contained therein, rendering the basis for this rejection moot.

With regards to the rejection of claims 5-11 and 16-17, applicants respectfully point out to the Examiner that any compositions that may be taught by Borron et al. do not contain recombinantly prepared SP-A. The relevant section of Borron et al. that discusses recombinant SP-A (page L680, column 2, paragraph 4) does not teach a pharmaceutical composition as presently claimed in claim 5. Rather, Borron et al. only discuss the generation of rSP-A alone by using insect cell lines and baculovirus vectors. No pharmaceutical composition comprising rSP-A, as required by present claims 5-11 and 16-17 is taught by Borron et al. Thus, the cited reference does not teach each and every element of claims 5-11 and 16-17 as required by *Verdegaal Bros. v. Union Oil Co. of California*.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection under 35 U.S.C. §102(a).

5. Rejection of claims 1-3, 5-11, 13-14 and 16-17 under 35 U.S.C. §102(a)

The Official Action states, in relevant part:

> Claims 1-3, 5-11, 13-14 and 16-17 are rejected under 35 U.S.C. 102(a) as being anticipated by LeVine et al.
>
> LeVine et al. teach a method of treating a pulmonary infection in a mouse by administering SP-A. The SP-A in the composition disclosed in LeVine et al. is considered "at least substantially the same as recombinant SP-A" and since it appears to have the same function as recombinant SP-A it is considered "the same as" recombinant SP-A.

RESPONSE

Applicants respectfully traverse this rejection. The Examiner has failed to establish a *prima facie* case of anticipation under 35 U.S.C. §102(a) because the cited reference fails to teach each and every element of the presently pending claims.

With regards to claims 1-3 and 14, applicants respectfully point out to the Examiner that claims 1-3 and 14 have been cancelled without prejudice to or disclaimer of the subject matter contained therein, rendering the basis for this rejection moot.

With regards to the rejection of claims 5-11, 13 and 16-17, applicants respectfully point out to the Examiner that LeVine et al. do not teach recombinantly prepared SP-A. Rather, LeVine et

al. only teach SP-A. As the basis of this rejection, the Examiner stated that "LeVine is considered to meet the limitations of Claims 5-11" because "the SP-A in the composition disclosed in LeVine et al. is considered 'at least substantially the same as recombinant SP-A' and since it appears to have the same function as recombinant SP-A it is considered 'the same as' recombinant SP-A." In this regard, applicants respectfully point out to the Examiner that the phrases "at least substantially the same as" and "which is the same as" have been deleted throughout the claims.

Thus, present claims 5-11, 13 and 16-17 require the presence of recombinantly prepared SP-A. Because LeVine et al. do not contain any teaching of recombinantly prepared SP-A, LeVine et al. do not teach each and every element of claims 5-11, 13 and 16-17 as required by *Verdegaal Bros. v. Union Oil Co. of California.* Thus, the Examiner has not established a *prima facie* case of anticipation.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection under 35 U.S.C. §102(a).

6. Rejection of claims 1-4 and 13-15 under 35 U.S.C. §102(b)

The Official Action states, in relevant part:

> Claims 1-4 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Kido et al.
>
> Kido et al. teach a method of treating a pulmonary viral infection with lung surfactant. Lung surfactant, which contains SP-A and SP-D, is disclosed by Kido et al. to be effective to treat the pulmonary viral infection. Thus, since the SP-A of the surfactant has the same sequence as recombinant SP-A and has the same function as recombinant SP-A, it is considered substantially the same as recombinant SP-A and the method disclosed therein is considered to meet the limitations of claims 13-15.
>
> The Examiner notes that the composition of Kido et al. is not lipid-free.

RESPONSE

Applicants respectfully traverse this rejection. The Examiner has failed to establish a *prima facie* case of anticipation under 35 U.S.C. §102(b) because the cited reference fails to teach each and every element of the presently pending claims.

With regards to claims 1-4 and 14, applicants respectfully point out to the Examiner that claims 1-4 and 14 have been cancelled without prejudice to or disclaimer of the subject matter contained therein, rendering the basis for this rejection moot.

With regards to the rejection of claims 13 and 15, applicants respectfully point out to the Examiner that these claims are drawn to a method for preventing or treating a pulmonary infection or inflammation by administering a lipid-free pharmaceutical composition comprising recombinant SP-A.

However, Kido et al. neither teach recombinantly prepared SP-A, nor, as conceded by the Examiner, a lipid-free pharmaceutical composition. Rather, Kido et al. teach lung surfactant generally and teach pharmaceutical compositions that contain lipids. As the basis of his rejection, the Examiner stated that "[l]ung surfactant, which comprises SP-A and SP-D, is disclosed by Kido et al. to be effective to treat the pulmonary viral infection" and "since the SP-A of the surfactant has the same sequence as recombinant SP-A and has the same function as recombinant SP-A, it is considered substantially the same as recombinant SP-A and the method disclosed therein is considered to meet the limitations of claims 13-15." In this regard, applicants again respectfully point out to the Examiner that the phrases "at least substantially the same as" and "which is the same as" have been deleted throughout the claims.

Thus, present claims 13 and 15 require that the pulmonary infection or inflammation be treated by administration of a

lipid-free pharmaceutical composition comprising recombinantly prepared SP-A. Because the Kido et al. reference does not contain any teaching of a lipid-free pharmaceutical composition comprising recombinantly prepared SP-A, Kido et al. do not teach each and every element of claims 13 and 15 as required by *Verdegaal Bros. v. Union Oil Co. of California.* Thus, the Examiner has not established a *prima facie* case of anticipation.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection under 35 U.S.C. §102(b).

7. Rejection of claims 1-3 and 16-17 under 35 U.S.C. §102(e)

The Official Action states, in relevant part:

> Claims 1-3 and 16-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Schilling et al.
>
> Schilling et al. disclose the recombinant production of SP-A for use as a medicament. Schilling et al. discuss administration of the SP-A protein (Column 8, lines 40-68). Thus, Schilling et al. is considered to teach a method making a medicament composition for treating pulmonary infection or inflammation comprising a carrier and recombinant SP-A.
>
> Claims 16-17 are also anticipated by Schilling et al. because the instructions and packaging of a composition is not considered to patentably distinguish the compositions over the prior art.

RESPONSE

Applicants respectfully traverse this rejection. The Examiner has failed to establish a *prima facie* case of anticipation under 35 U.S.C. §102(e) because the cited reference fails to teach each and every element of the presently pending claims.

With regards to claims 1-3, applicants respectfully point out to the Examiner that claims 1-3 have been cancelled without prejudice to or disclaimer of the subject matter contained therein, rendering the basis for this rejection moot.

With regards to the rejection of claims 16 and 17, applicants respectfully point out to the Examiner that these claims are drawn to an article of manufacture comprising 1) a lipid-free pharmaceutical composition comprising an active component wherein the active component comprises recombinant surfactant protein A (rSP-A); and 2) a packaging material comprising a label or package insert which indicates that the active component is useful for preventing or treating a pulmonary microbial infection or inflammation.

However, Schilling et al. contain no teaching of either of these required elements of claims 16 and 17. Rather, Schilling et al. teach recombinantly produced alveolar surfactant protein

(ASP) generally, "which are mixtures of relatively high molecular weight, relatively water soluble proteins of about 32 kd (32K ASP) and of lower molecular weight, hydrophobic proteins of about 5-20 kd (10K ASP)." This is not a teaching of a lipid-free pharmaceutical composition comprising a pharmaceutically active component, wherein the active component comprises a recombinantly prepared surfactant protein A.

Further, Schilling et al. do not contain any teaching of a packaging material comprising a label or package insert which indicates that the active component is useful for preventing or treating a pulmonary microbial infection or inflammation.

Thus, because the Schilling et al. reference does not contain any teaching of a lipid-free pharmaceutical composition comprising recombinantly prepared SP-A, Schilling et al. do not teach each and every element of claims 16 and 17 as required by *Verdegaal Bros. v. Union Oil Co. of California.* Thus, the Examiner has not established a *prima facie* case of anticipation.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection under 35 U.S.C. §102(e).

8. Rejection of claims 1-17 under 35 U.S.C. §103(a)

The Official Action states, in relevant part:

> Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCormack et al. and Borron et al. in view of Madan et al., LeVine et al., King et al. and Schilling et al.
>
> McCormack et al. and Borron et al. provide evidence that at the time of the invention, recombinant production of SP-A was routine in the art. Moreover, Borron et al. provide evidence that the recombinant SP-A was functionally similar to SP-A purified from nature and is similarly effective in inhibiting T lymphocyte proliferation. This evidence suggests that the recombinant form of SP-A would be equally effective in protecting against pathogens entering the lungs. McCormack et al. and Borron et al. do not teach the use of recombinant SP-A in vivo.
>
> Madan et al., LeVine et al., King et al., and Schilling et al. provide evidence that those of skill in the art at the time of the invention were well aware that SP-A could be effective in protecting or treating against various lung infections or disorders. Madan et al, teach that SP-A and SP-D are involved in the initial protective immunity against A. fumigatus. Based on the ability of these surfactant proteins to reduce histamine released by sensitized cells on allergen exposure, Madan, et al. suggest that SP-A and SP-D may be used therapeutically in the treatment of allergic disorders such as allergic bronchopulmonary Aspergillosis. LeVine et al. teach that an SP-A composition (that does not contain lipids) administered to mice enhances the pulmonary clearance of Group B Streptococcus. LeVine et al. does not teach the source of the SP-A. Wang et al. teach and provide evidence that SP-A and SP-D are able to suppress allergen-induced lymphocyte proliferation and histamine release in asthmatic children. King et al. indicate that the functions of SP-A include modulation of the immune response, regulation of surfactant metabolism affecting surfactant secretion, mitigation

of the effects of inhibitors of surfactant function, and reduction of superoxide production by alveolar macrophages. King et al. teach that SP-A is reduced in infants with hyaline membrane disease, and patients with acute respiratory distress syndrome. Schilling et al. suggest that recombinant SP-A could be used in the treatment of respiratory distress syndrome and related respiratory disease such as pneumonia and bronchitis.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to make a medicament containing recombinant SP-A and a suitable carrier and to use that medicament in a method of treating pulmonary infection or inflammation. McCormack et al. and Borron et al. provide evidence that recombinant production of SP-A was routine at the time of the invention and Madan et al., LeVine et al., King et al., and Schilling et al. all provide evidence that those of skill in the art were aware that SP-A would be effective in treating pulmonary infections and disorders. Madan et al. suggests that SP-A could be used therapeutically and Schilling et al. suggests using the recombinant form of SP-A in treatments for respiratory distress, pneumonia and bronchitis. The references also indicate that SP-D would also be effective. Therefore, one of ordinary skill in the art would have been motivated to make and use the medicament compositions containing recombinant SP-A for use in methods of treatment because recombinant technology would allow an easier method for obtaining large amounts of protein, a more purified form of the protein and an easier way to modify the protein as necessary for the needs at hand.

RESPONSE

With regards to the rejection of claims 1-4 and 14, applicants respectfully point out to the Examiner that claims 1-4 and 14 have been cancelled without prejudice to or disclaimer

of the subject matter contained therein, rendering the basis for this rejection moot.

As to the rejection of pending claims 5-13 and 15-17, applicants respectfully traverse the rejection of these claims. The references of record do not teach or suggest applicants' inventive subject matter as a whole as recited in the claims. Thus, the Examiner has failed to establish a *prima facie* case of obviousness against the presently rejected claims.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

a. The Presently Claimed Invention

The presently pending claims are drawn to 1) a lipid-free pharmaceutical composition comprising a pharmaceutically active component and suitable carrier therefore, wherein the active component comprises recombinant surfactant protein A (rSP-A); 2) methods of treating or preventing a pulmonary infection or inflammation by administering the pharmaceutical composition; and 3) articles of manufacture containing the pharmaceutical composition.

b. Teaching of the "Primary" McCormack et al. reference

McCormack et al. does not teach a lipid-free pharmaceutical composition comprising a pharmaceutically active component and suitable carrier therefore, wherein the active component comprises recombinant surfactant protein A (rSP-A) as required by the present claims. Rather, McCormack et al. teach that "recombinant SP-A is able to inhibit the secretion of phospholipid from isolated type II cells and to aggregate lipid vescicles independent of the presence of *N*-linked carbohydrate or the site of glycosylation." (see Abstract)

c. Teaching of the "Primary" Borron et al. reference

The relevant section of Borron et al. that discusses recombinant SP-A (page L680, column 2, paragraph 4) does not teach a lipid-free pharmaceutical composition as presently claimed in claim 5. Rather, Borron et al. only discuss the generation of rSP-A alone using insect cell lines and baculovirus vectors.

d. Deficiencies of the Teachings of the "Primary" References

Thus, the Borron et al. and McCormack et al. references do not contain any teaching of a lipid-free pharmaceutical composition as presently claimed in claim 5. Further, the Borron et al. and McCormack et al. references do not contain any teaching of methods of treating or preventing a pulmonary infection or inflammation by administering the lipid-free pharmaceutical composition of claim 5. Further, the Borron et al. and McCormack et al. references do not contain any teaching of an article of manufacture containing the lipid-free pharmaceutical composition of claim 5.

The secondary references cited by the Examiner do not remedy the deficient teachings of the Borron et al. and McCormack et al. references.

e. Teaching of the "Secondary" Madan et al. Reference

The teachings contained in the Madan et al. reference do not remedy the deficient teachings of the Borron et al. and McCormack et al. references. In particular, Madan et al. do not teach a lipid-free pharmaceutical composition comprising a pharmaceutically active component and suitable carrier therefore, wherein the active component comprises recombinant surfactant protein A (rSP-A).

Rather, Madan et al. teach that "SP-A and SP-D significantly reduced histamine release from the sensitized basophils by the *A. fumigatus* allergens" but "surfactant proteins were not able to bind them and thus would not be expected to completely block histamine release" in the treatment of allergic bronchopulmonary Aspergillosis (ABPA). (See page 248, column 1, last paragraph). As such, Madan et al. clearly lacks any teaching of recombinant SP-A and any teaching of a pharmaceutical composition comprising recombinant SP-A.

f. Teaching of the "Secondary" LeVine et al. Reference

The teachings contained in the LeVine et al. reference do not remedy the deficient teachings of the Borron et al. and McCormack et al. references. In particular, LeVine et al. do

not teach a lipid-free pharmaceutical composition comprising a pharmaceutically active component and suitable carrier therefore, wherein the active component comprises recombinant surfactant protein A (rSP-A).

Rather, LeVine et al. only teach the benefits of SP-A in pulmonary clearance of Group B Streptococcus (GBS) infection in mice. As such, LeVine et al. clearly lacks any teaching of recombinant SP-A and any teaching of a pharmaceutical composition comprising recombinant SP-A.

g. Teaching of the "Secondary" King et al. Reference

The teachings contained in the King et al. reference also do not remedy the deficient teachings of the Borron et al. and McCormack et al. references. In particular, King et al. do not teach a lipid-free pharmaceutical composition comprising a pharmaceutically active component and suitable carrier therefore, wherein the active component comprises recombinant surfactant protein A (rSP-A).

Rather, King et al. only teach that certain physiochemical properties of surfactant that have been attributed to SP-A include modulation of the immune response or phagocytosis; regulation of surfactant metabolism affecting surfactant

secretion or reuptake; and mitigation of the effects of inhibitors of surfactant function found in the alveolar fluid of HMD patients. As such, King et al. clearly lacks any teaching of recombinant SP-A and any teaching of a pharmaceutical composition comprising recombinant SP-A.

h. Teaching of the "Secondary" Schilling et al. Reference

The teachings contained in the Schilling et al. reference also do not remedy the deficient teachings of the Borron et al. and McCormack et al. references. In particular, Schilling et al. do not teach a lipid-free pharmaceutical composition comprising a pharmaceutically active component and suitable carrier therefore, wherein the active component comprises recombinant surfactant protein A (rSP-A).

Rather, Schilling et al. teach recombinantly produced alveolar surfactant protein (ASP) generally, "which are mixtures of relatively high molecular weight, relatively water soluble proteins of about 32 kd (32K ASP) and of lower molecular weight, hydrophobic proteins of about 5-20 kd (10K ASP)." This is not a teaching of a lipid-free pharmaceutical composition comprising a pharmaceutically active component, wherein the active component comprises a recombinantly prepared surfactant protein A.

i. The Cited References Do Not Teach Each And Every Element Of The Present Claims

Thus, as outlined above, the references cited by the Examiner fail to teach each and every element of the presently pending claims. As such, the Examiner has failed to establish a *prima facie* case of obviousness.

j. There is No Motivation to Combine Any of the Six References Cited by the Examiner

Further, one of ordinary skill in the art would have had no teaching, suggestion or motivation to combine any of the six references to arrive at the presently claimed invention at the time the invention was made.

"When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references." *In re Rouffet*, 149 F.3d 1350, 1355, 47 U.S.P.Q.2D (BNA) 1453, 1456 (Fed. Cir. 1998) (citing *In re Geiger*, 815 F.2d 686, 688, 2 U.S.P.Q.2D (BNA) 1276, 1278 (Fed. Cir. 1987)). "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting

the combination." *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 U.S.P.Q. (BNA) 929, 933 (Fed. Cir. 1984). Although the suggestion to combine references may flow from the nature of the problem, see *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573, 37 U.S.P.Q.2D (BNA) 1626, 1630 (Fed. Cir. 1996), "defining the problem in terms of its solution reveals improper hindsight in the selection of the prior art relevant to obviousness," *Monarch Knitting Mach. Corp. v. Sulzer Morat Gmbh*, 139 F.3d 877, 880, 45 U.S.P.Q.2D (BNA) 1977, 1981 (Fed. Cir. 1998). Therefore, "when determining the patentability of a claimed invention which combines two known elements, 'the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.'" *In re Beattie*, 974 F.2d 1309, 1311-12, 24 U.S.P.Q.2D (BNA) 1040, 1042 (Fed. Cir. 1992) (quoting *Lindemann Maschinenfabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1462, 221 U.S.P.Q. (BNA) 481, 488 (Fed. Cir. 1984).

Even if the references contained all of the required elements of the presently pending claims, which they clearly do not as outlined above, the Examiner has also not provided an adequate "teaching, suggestion, or motivation to combine" these

six references. Instead, the Examiner has relied on improper hindsight logic in an attempt to reconstruct the presently claimed invention. Such a teaching cannot be willed into existence. Thus, for the Examiner to suggest that a person of ordinary skill in the art would be motivated to look at each of these six references together in order to prepare the presently claimed invention is improper.

As such, a person of ordinary skill in the art would have had no motivation to combine the teachings of the six references to arrive at the presently claimed invention at the time the invention was made.

k. No *Prima Facie* Case Has Been Established

Thus, the Examiner has failed to establish a *prima facie* case of obviousness for two reasons: 1) The six references do not contain each and every element of the presently pending claims as required by *In re Wilson;* and 2) the cited references contain absolutely no suggestion or incentive that would have motivated the skilled artisan to combine the six references as required by *In re Rouffet.*

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection under 35 U.S.C.

§103(a).

CONCLUSION

In view of the foregoing, applicants respectfully request the Examiner to allow all claims pending in this application.

If the Examiner has any questions or wishes to discuss this matter, the Examiner is welcomed to telephone the undersigned attorney.

Respectfully submitted,

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